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Serial No. 08/961,443

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of
Townes, Tim M. et al.

Serial No. 08/961,443

Filed: October 10, 1997

For: TRANSGENIC ANIMALS THAT PRODUCE HEMOGLOBIN

Group Art Unit: 1632

Examiner: Jill Martin

DECLARATION UNDER 37 C.F.R. 1.132

THE TOWNES DECLARATION 1

BOX FEE AMENDMENT
Commissioner for Patents
Washington, D.C. 20231

NEEDLE & ROSENBERG, P.C.
Suite 1200, The Candler Building
127 Peachtree Street, N.E.
Atlanta, Georgia 30303-1811

April 10, 2002

Sir:

1. I, Tim Townes, a citizen of the United States, residing at 4687 Bridgewater Rd, Birmingham, Al 35243, declare that:

2. I have a Ph.D. degree in Microbiology from the University of Tennessee in Knoxville. I have been conducting research in the field of Molecular Genetics since 1982 and am a co-author of at least 50 publications relating to hemoglobin and hemoglobin transgenesis. I am currently Professor and Chairman of the Department of Biochemistry and Molecular Genetics at the University of Alabama at Birmingham.

3. I am a co-inventor of the subject matter in United States Patent Application No. 08/961,443.

4. I have reviewed

a. United States Patent Application No. 08/961,443

b. an Office Action dated December 10, 2001, issued in U.S. Patent Application No. 08/961,443

c. Campbell et al., Biology of Reproduction, 50:1385-1393 (Exhibit 1)

d. the Abstract entitled "Live lambs by nuclear transfer from an established cell line," by K.H.S. Campbell, J. McWhir, W.A. Ritchie and I. Wilmut, published in Theriogenology, Vol. 45(1):287-287 (January, 1996) ("Wilmut Abstract") (Exhibit 2)

5. After reviewing the Office Action dated December 10, 2001, I understand that the examiner believes that as of March 6, 1996, only mice could be produced from cultured cell lines.

6. After reviewing United States Patent Application No. 08/961,443, I understand the application, along with the general knowledge in the field of producing whole animals from cultured cells, to teach how to produce both non-mouse mammals and mice from cultured cells.

7. As of March 6, 1996 there were two ways to obtain whole animals from cultured cells: 1) Nuclear transfer technology and 2) ES cell technology.

8. As of January 1996, methods for culturing cells which could be successfully used in nuclear transfer experiments were known to those producing whole animals from cultured cells. To be able to perform nuclear transfer a researcher needs to know the conditions under which the donor nucleus is propagated, the conditions under which the recipient oocyte is maintained, and the conditions for transferring the donor nucleus to the recipient oocyte. Campbell et al,, (Exhibit 1) along with the Wilmut Abstract (Exhibit 2) teach all three of these conditions for nuclear transfer of cultured cells.

9. Campbell teaches the recovery of oocytes and embryos, procedures for nuclear transfer of blastocyst nuclei, activation, culture of reconstructed embryos, and transfer to final recipients.

10. Thus, as of June 1994, the publication date of Campbell et al., methods for successful whole animal production from nuclear transfer techniques were known.

11. In the Wilmut Abstract (Exhibit 2) the conditions for performing nuclear transfer with cultured cells rather than blastocyst cells are altered slightly. The cultured donor cells were flushed with PBS/1.0% FCS and all oocytes were cultured in calcium-free M2 medium until the time of activation.

12. In addition, the Wilmut Abstract (Exhibit 2) teaches that certain procedures should be performed prior to nuclear transfer, stating "Prior to nuclear transfer, donor cells were cultured in medium containing 0.5% serum for 5 days to induce quiescence. Embryos were reconstructed using cells between passages 6 and 13 by fusion."

13. The Wilmut Abstract (Exhibit 2) teaches the modifications of Campbell et al. (Exhibit 1) needed to perform whole animal production from cultured cells.

14. Thus, as of at least January 1996, the date of the Wilmut Abstract (Exhibit 2) live lambs from cultured cell lines by nuclear transfer had successfully been produced, and the techniques for performing these activities had been shared with the scientific community.

15. Thus, with the methods known in the art, including those disclosed in Campbell et al. (Exhibit 1) and those disclosed in Wilmut et al. (Exhibit 2) and summarized in paragraphs 9-13 above, one who produces whole animals from cultured cells would be able to make a non-mouse mammal, in addition to a mouse, from a cultured cell, based on United States Patent Application No. 08/961,443 and that which was known in the art as of March 6, 1996.

16. I further declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that

these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or document or any patent issuing therefrom.

Tim Townes

Tim Townes, Ph.D.

04/10/02

DATE